DEC 1 2 2006

EXHIBIT 2
510(k) Summary
510(k) Number K052465

Heartsine Technologies, Inc.
105 Terry Drive
Newtown, PA 18940
Phone: 1-215-860-8100
Fax: 1-215-860-8192

December 6, 2006

Contact: Alan B. Hershman, RAC

1. **Identification of the Device:**
   Proprietary-Trade Name: samaritan® Pediatric-Pak (Model SPP 351)
   Classification Names: Defibrillators, automatic, external 74 MKJ
   Common/Usual Name: Automated external defibrillator and electrodes.

2. **Equivalent legally marketed device:** Medtronic LIFEPAK 500, K052057

3. **Indications for Use:**
   The samaritan Pediatric-Pak (Model SPP 351) is indicated for use to treat patients in cardiopulmonary arrest who are unconscious, without a pulse and not breathing spontaneously. They should only be used by personnel who have been trained in its operation.

   The samaritan Pediatric-Pak is specially designed for use with the samaritan PAD (Model SAM 300P) only. The SAM 300P, in conjunction with the Pediatric Pak, allows the samaritan® PAD to deliver lower-energy therapy to children from 1 year of age to 8 years or up to 55lbs (25kg). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.

4. **Description of the Devices:**
   The samaritan® Pediatric-Pak is intended as a direct replacement for the Adult Pad-Pak but for use with children between the ages of 1 year and 8 years or 55 pounds (25 kilograms) in weight. The electrodes and lead wires are identical in materials and construction to those used in the adult samaritan® Pad-Pak, cleared under K042088 for use with patient above 8 years old or 55 pounds in weight. They are use in the same way as with the adult samaritan® PAD-Pak. The energy reduction required for children is accomplished by means of purely resistive attenuation in concert with a separate energy look-up table incorporated into the PAD embedded software. The Pediatric-Pak incorporates a magnet which is sensed, on insertion, by the host PAD which automatically prompts the user "child patient" and, while the Pediatric-Pak is in position, uses the Pediatric look-up table to define the voltage and duration of the therapeutic shock commensurate with the required energy deliverable (50 Joules), taking into account the attenuation by the resistors incorporated into the Pediatric-Pak. The electrodes are sealed inside poly/foil, peelable pouches of the same materials and construction as the current adult PAD-Pak electrodes. The purely resistive attenuator circuit board is enclosed inside the Pediatric-Pak requiring a slightly lengthened version of the current PAD-Pak molded housing. A different color scheme (pink) is used to help differentiate the samaritan Pediatric-Pak from their adult counterparts. The product labeling for the samaritan® Pediatric-Pak indicates a "anterior/posterior" placement to be preferred, while allowing for the typical adult "apex/sternum" placement under some circumstances.

5. **Safety and Effectiveness, comparison to predicate device:**
The results of bench testing and validation against a pediatric heart rhythm database indicates that the HeartSine Technologies samaritan Pediatric-Pak is substantially equivalent in safety and effectiveness to the predicate devices.

6. Substantial Equivalence Chart

Company	**Medtronic LIFEPAK® 500**	**Heartsone Technologies**
Model No.	Medtronic Physio-Control Infant/Child Reduced Energy Electrodes	Reduced Energy Pediatric Electrode Pads For the samaritan® PAD
510(k) No.	K052057	K052465
Indications	For automated defibrillation of infants and children up to approx. 8 years of age or 25 kg weight.	For automated defibrillation of children from 1 year to 8 years of age or 55 lbs (25 kg) weight.
Energy Reduction	4:1	Fixed at 50 Joules
Technology	Encapsulated resistive divider part of disposable electrode assembly	Encapsulated resistive divider part of disposable electrode/battery pack assembly for the PAD model.

7. **Conclusion**
After analyzing testing data and the predicate device, it is the conclusion of HeartSine Technologies, Inc that the samaritan® Pediatric-Pak in conjunction with the samaritan® PAD Model 300P are as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HeartSine Technologies, Inc
c/o Alan B. Hershman, RAC
Quality and Regulatory Affairs
105 Terry Drive
Newtown, PA, 18940

DEC 1 2 2006

Re: K052465
Trade/Device Name: Samaritan Pediatric-Pak (Model SPP351)
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: November 2, 2006
Received: November 7, 2006

Dear Mr. Hershman:

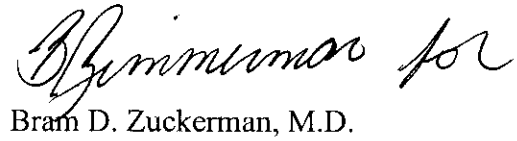
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052465

Device Name:

The samaritan® Pediatric-Pak (Model SPP 351)

Indications for Use:

The samaritan® Pediatric-Pak (Model SPP 351) is indicated for use to treat patients in cardiopulmonary arrest who are unconscious, without a pulse and not breathing spontaneously. They should only be used by personnel who have been trained in its operation.

The samaritan® Pediatric-Pak is specially designed for use only with the samaritan® PAD (Model SAM 300P). This product allows the samaritan PAD to deliver lower-energy therapy to children from 1 year of age to 8 years or up to 55lbs (25kg).
DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number k052465

Prescription Use X (21 CFR 801 Subpart D) or Over-The-Counter Use ___ (21 CFR 807 Subpart C)